

BIRD ET AL. -- 10/019,236  
Client/Matter: 051241-0290458

### REMARKS

#### **Patentability Remarks**

On pages 2-4 of the official action, the examiner rejected claims 1, 4-13, 15, 16, 23-26, 28-30, 32-36, and 39-61 under 35 U.S.C. §103(c) as being obvious over U.S. Patent No. 5,723,446 (hereinafter Gray *et al.*) in view of U.S. Patent No. 5,840,860 (hereinafter Annison *et al.*).

The applicants would like to further submit that the examiner cited Annison *et al.* for the alleged teaching that this reference discloses a fatty acid delivery system comprised of a fatty acid source wherein the carbohydrate serves as the carrier wherein one of the preferred carriers is starch. The applicants submit that this secondary reference does little to overcome the failings of the primary document, Gray *et al.*

The applicants' claimed enteral formulation, in contrast, has a maximum fatty acid delivery agent percentage of only 5%. One of skill in the art would not expect a 5% complex fatty acid delivery agent concentration to be an adequate amount to provide the colonic benefits of the SCFA or other fatty acids as a replacement of normal fiber supplements. Yet, in fact, the applicants submit that for the first time that their teachings give the unexpected result of a quantum increase in the capacity to alleviate nutritional deficiencies in the large bowel via the enteral tube by using the recited fatty acid delivery agents at a 0.25% to 5% weight ratio to the overall formulation.

In contrast, Annison *et al.* did not teach that the fatty acid delivery agent could be administered as a nasogastric formulation. Also, Annison *et al.* fail to indicate that delivery through a nasogastric tube can be achieved by decreasing the concentration of the fatty acid delivery agent (starch)(*i.e.* to levels of 0.25 to 5.0%) relative to the levels shown in the examples of Annison *et al.*, and yet still provide a beneficial effect as assessed by the indicators shown in the data of the present invention. In fact, the levels of the fatty acid delivery agent starch disclosed in Annison *et al.*'s *in vivo* experiments (Tables 3 and 11) were calculated to be 15%, which would clog the enteral tube. Specifically, the enteral formulation of Annison *et al.* would be undeliverable using a enteral tube for delivery via the nasogastric route with the 15% percent of starch in the fatty acid deliver agents due the viscosity constraints inherent in a 15% fatty acid delivery agent level. Thus Annison *et al.* teaches a percent weight/ratio of starch (as the fatty acid delivery agent) that actually teaches away from enteral formulation (0.25 to 5.0% weight ration of fatty acid delivery agent) disclosed by the applicants.

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Accordingly, the applicants respectfully submit that one of skill in the art would not be directed to an enteral formulation for nasogastric delivery comprising (a) an amino acid source, (b) a carbohydrate source, (c) a lipid source, (d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, the covalent bonding providing a protective effect to both the carrier and fatty acid from degradation in the stomach or small intestine, said carrier being any one of a starch, a non-starch polysaccharide, or oligosaccharide, wherein the fatty acid delivery agent being present in the formulation range of 0.25% w/v through to 5% w/v, and wherein the formulation can be delivered through an enteral feeding tube in view of Annison *et al.*

In summary, the applicants submit the primary reference, Gray *et al.*, in view of the secondary reference, Annison *et al.*, neither teach nor suggest the applicants' claimed invention. Accordingly, without such teaching or suggestion, the examiner has not established a prima facie case of obviousness. Therefore, withdrawal of the rejection of claims 1, 4-13, 15, 16, 23-26, 28-30, and 39-61 pursuant to 35 U.S.C. §103(a) is respectfully requested.

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### III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form of allowance, and such action is hereby solicited. If any point remains at issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number below.

Respectfully submitted,  
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